UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,122	01/13/2004	Terrance C. Dahl	269.PC	3821

7590 08/14/2008

Mark Bosse
Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404

EXAMINER	
CHONG, YONG SOO	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
08/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/757,122	DAHL ET AL.	
	Examiner	Art Unit	
	YONG S. CHONG	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-35,41-51 and 54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-35,41-51 and 54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/22/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 5/22/08. Claims 1-23, 36-40, 52-53, 55-57 have been cancelled. Claims 24-35, 41-51, 54 are pending. Claims 24, 26-28, 30, 49 have been amended. Claims 24-35, 41-51, 54 are examined herein.

Applicant's arguments have been fully considered but found not persuasive. The rejections of the last Office Action are maintained for reasons of record and repeated below for Applicant's convenience.

Claim Objections

Claims 24-35 are objected to because of the following informalities: the term "physiologically salt" is grammatically incorrect. Applicant is advised to amend the term to "physiologically acceptable salt" as recited in the specification. Appropriate correction is required.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41-51, 54 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 41-51, 54 of copending Application No. 10/540,782.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's request to address this ground of rejection as soon as allowable subject matter has been identified is acknowledged.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24-35 of copending Application No. 10/540,782. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a pharmaceutical formulation comprising GS-7340 and emtricitabine in the claimed amounts and dosage forms.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 24-35, 41-51, 54 are rejected under 35 U.S.C. 103(a) as being obvious over Buelow et al. (US Patent 7,094,413 B2) in view of Becker et al. (US Patent Application 2002/0119443 A1).

The instant claims are directed to a pharmaceutical formulation comprising GS-7340, emtricitabine, and a protease inhibitor (PI).

Buelow et al. teach treating HIV infected patients (abstract) with a pharmaceutical composition comprising suitable anti-retroviral agents (col. 3, lines 64-65). Preferred anti-retroviral agents include reverse transcriptase inhibitors such as emtricitabine, lamivudine (3TC), and various derivatives thereof (col. 35-52). Further, protease inhibitors, such as Indinavir, Saquinavir, and Ritonavir, may be used as anti-retroviral agents. Furthermore, combinations of a plurality of antiviral agents may be used, thus increasing the efficacy of the therapy and lessening the occurrence of resistance to the anti-viral drugs (col. 4, lines 15-23). The pharmaceutical composition may be formulated in a unit dosage form, such as solids, pills, tablets, and capsules (col. 24, lines 11-15) for oral delivery. Pharmaceutically acceptable carriers may be used, for example microcrystalline cellulose, magnesium stearate (col. 24, lines 26-38), and starch (col. 29, line 56).

The amount administered to the host will vary depending upon what is being administered, the purpose of the administration, the state of the host, the manner of administration, the number of administrations, interval between administrations, and the

like. Determining dosages and times of administration for a therapeutically effective amount are well within the skill of the ordinary person in the art. For any compounds used in the present invention, therapeutically effective dose is readily determined by methods well known in the art. Generally, administration is in the range of 1-25 mg/kg body weight of the host, which equates to 70 mg to 1.75 g for an average human of 70 kg (col. 28, lines 6-59). The host or subject may be any mammal including domestic animals, pets, laboratory animals, primates, and humans (col. 29, lines 1-3).

Generally, mere optimization of ranges will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "When the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimal or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also *In re Peterson*, 315 F. 3d at 1330, 65 USPQ 2d at 1382 "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." MPEP 2114.04.

Buelow et al. also discloses therapeutic combinations disclosed herein in the form of a kit or packaged formulation, which includes appropriate instructions (col. 31, lines 10-24).

However, Buelow et al. fail to specifically disclose GS-7340.

Becker et al. disclose the general teaching the GS-7340 (section 0040) possesses anti-retroviral activity (abstract) for the administration to HIV infected patients

(sections 0003-0009). Oral 10 mg-eq/kg dosages of GS-7340 are disclosed (section 0169).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to have combined GS-7340 as disclosed by Becker et al. in the pharmaceutical composition comprising emtricitabine as disclosed by Buelow et al.

A person of ordinary skill in the art would have been motivated to have combined GS-7340 as disclosed by Becker et al. in the pharmaceutical composition comprising emtricitabine as disclosed by Buelow et al. because: (1) both GS-7340 and emtricitabine are well known as anti-retroviral agents; (2) both Buelow and Becker et al. disclose administration to HIV infected patients; and (3) Buelow et al. teach that combinations of a plurality of antiviral agents may be used, thus increasing the efficacy of the therapy and lessening the occurrence of resistance to the anti-viral drugs. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating a viral infection in a patient by administrating a pharmaceutical composition comprising GS-7340, emtricitabine, and a protease inhibitor (PI).

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... The idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Examiner respectfully reminds Applicant that the limitations regarding "chemically stable combination" as recited in claims 47-51 and 54 are given little patentable weight since a composition and its properties are inseparable.

"Products of identical chemical composition can not have mutual exclusive properties." Any properties exhibited by or benefits from are not given any patentable weight over the prior art provided the composition is inherent. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the disclosed properties are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to the applicant to show that the prior art product does not inherently possess the same properties as the instantly claimed product.

Response to Arguments

Applicant argues that there are many possible combinations of anti-retrovirals disclosed in the art, covering the same and different classes of compounds. Applicant asserts that a prima facie case of obviousness cannot be made here absent some specific rationale for combining specifically GS-7340 with specifically emtricitabine. Given all the possible combinations, it would not be even be obvious to try the specific claimed combination with a reasonable expectation of success.

This is not persuasive because Applicant is making broad statements about anti-retroviral drugs without comprehending the context in which the rejection was made. While there are many possible combinations of anti-retrovirals disclosed in the art,

covering the same and different classes of compounds, the argument for or against combining various anti-retroviral drugs should be restricted to the context of treating HIV infected patients as disclosed by both Buelow and Becker et al. Applicant is reminded that Buelow et al. teach that combinations of a plurality of antiviral agents may be used, thus increasing the efficacy of the therapy and lessening the occurrence of resistance to the anti-viral drugs. Applicant is also reminded that the cited prior art references do not disclose all possible classes and/or combinations of known anti-retrovirals, but a limited number of anti-retroviral drugs to treat HIV infected patients. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating a viral infection in a patient by administrating a pharmaceutical composition comprising GS-7340, emtricitabine, and a protease inhibitor (PI).

Applicant asserts that the inventive combination is chemically stable since the claims recite that the combination is required to be chemically stable. Applicant requests the Examiner to address this issue.

As stated in the last two paragraphs of the rejection in the last Office Action, it is the Examiner's position that since the inventive combination has been taught by the cited prior art, any or all properties related to the combination is inherent. In this case, the combination of GS-7340 and emtricitabine is inherently chemically stable because all components of the composition have been accounted for. Examiner cannot understand how the same combination of active agents can be chemically stable and unstable at the same time. Applicant is encouraged to submit factual evidence that the

combination of GS-7340 and emtricitabine, as taught by the cited prior art, is not chemically stable when compared to the instant invention in a side by side analysis.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YONG S. CHONG whose telephone number is (571)272-8513. The examiner can normally be reached on M-F, 9-66.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong S Chong/
Examiner, Art Unit 1617

YSC